MAR 1 8 2005

EXHIBIT 2

K073577

Medlink Imaging Inc.
200 Clearbrook Rd
Elmsford NY 10523
Tel 800-456-7800
Fax 888-437-9729
September 30, 2003
Contact: John Garcia

510(k) Summary

1. **Identification of the Devices:**
   Proprietary-Trade Name: "Pulmoscan," "Uniscan," and "Pulmoscan-T" Digital Radiographic Systems
   Classification Name: Stationary X-Ray System, Product Code KPR and MKP
   Common/Usual Name: Stationary or Transportable X-Ray System

2. **Equivalent legally marketed devices** This product is similar in function to the Siemens Multix FD and Thorax FD Stationary X-Ray System (K983732)

3. **Indications for Use (intended use)** - The "Uniscan" model is a stationary general-purpose diagnostic (universal) system for obtaining standard planar X-ray images of the bone structure and soft tissues of a patient in the standing, sitting and lying position .
   - The "Pulmoscan" model is a stationary specialized-purpose diagnostic system for mass examination (screening) of wide groups of population, first of all, in polyclinics at the stage of before-doctor examination with the purpose of early diagnostics of the thorax organs.
   - The "Pulmoscan-T" model is a mobile specialized-purpose diagnostic system, particularly, for mass examination (screening) of wide groups of population directly at the places of their maximum concentration (in educational institutions and at enterprises), in remote areas (villages, military units), in institutions with the special access regime (refugees camps, penal jurisdiction) with the purpose of early diagnostics of the thorax organs.

4. **Description of the Device:** The principal of functioning of the DRS system is based on:
   - generation of highly stable low-energy X-ray radiation (from 40 up to 150 keV) with controllable parameters (voltage, current, time, exposure duration) by means of an X-ray source connected to the X-ray power supply unit;
   - formation of a flat narrow with the width D fan-shaped X-ray beam with the possibility of masking according to the radiation angle a by means of the adjustable diaphragm;
   - exposure of the area of the patient's body to be examined (input dimensions A ' B) by scanning with a flat X-ray beam in the field of the scanning angle b with the possibility of specifying and visual control of the scanning (exposure) field;
   - magnification of the planar X-ray image of the patient with the specified enlargement by projecting it to the scanning X-ray detector located at a

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considerable distance from the patient;
- obtaining the digital X-ray image of the area to be examined by means of the scanning X-ray detector (on the basis of a linear matrix multielement semiconductor detector), converting the absorbed X-ray radiation into digital form;
- formation of the two-dimensional digital projection image on the computer monitor with the possibility of manipulation and archiving by means of the special software

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench and user testing indicates that the new device is as safe and effective as the predicate devices.

6. **Substantial Equivalence Chart, "Pulmoscan," "Uniscan," and "Pulmoscan-T" Radiographic Systems**

Characteristic	Siemens Multix FD and Thorax FD Stationary X-Ray System (K983732)	"Pulmoscan," "Uniscan," and "Pulmoscan-T" Radiographic Systems
Intended Use:	Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.	SAME
Performance Standard	21 CFR 1020.30	SAME
Electrical safety	Electrical Safety per Underwriters Laboratories Standard UL-2601(IEC-60601) and IEC 60601, Underwriters Laboratories Standard UL187: UL Standard for Safety for X-Ray Equipment, CE Marking Requirements	SAME

7. **Conclusion**

After analyzing both bench and user testing data, it is the conclusion of Medlink Imaging that the "Pulmoscan," "Uniscan," and "Pulmoscan-T" Radiographic Systems are as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Medlink Imaging, Inc.
% Daniel Kamm, P.E.
Regulatory Affairs
Kamm & Associates
PO Box 7007
DEERFIELD IL 60015

AUG 21 2013

Re: K033577
Trade/Device Name: "Pulmoscan", "Uniscan", and "Pulmoscan-T" Radiographic Systems
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray System
Regulatory Class: II
Product Code: KPR and MQB
Dated: February 3, 2005
Received: February 22, 2005

Dear Mr. Kamm:

This letter corrects our substantially equivalent letter of March 18, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

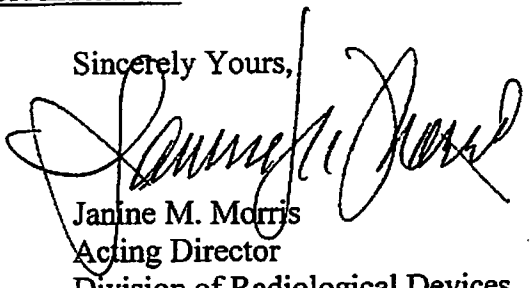
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,



Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

i) Indications for Use

510(k) Number K033577

Device Name: "Pulmoscan," "Uniscan," and "Pulmoscan-T" Radiographic Systems

Indications for Use:
- The DRS system of the "Uniscan" model is a stationary general-purpose diagnostic (universal) system for obtaining standard planar X-ray images of the bone structure and soft tissues of a patient in the standing, sitting and lying position
- The DRS system of the "Pulmoscan" model is a stationary specialized-purpose diagnostic system for mass examination (screening) of wide groups of population, first of all, in polyclinics at the stage of before-doctor examination with the purpose of early diagnostics of the thorax organs.
- The DRS system of the "Pulmoscan-T" model is a mobile specialized-purpose diagnostic system, particularly, for mass examination (screening) of wide groups of population directly at the places of their maximum concentration (in educational institutions and at enterprises), in remote areas (villages, military units), in institutions with the special access regime (refugees camps, penal jurisdiction) with the purpose of early diagnostics of the thorax organs.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use _____
(Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K033577